DEC - 4 2003

K032309

510(k) Summary Statement

SUBMITTER:

Submitted on behalf of:

Company Name:	NoveLens®, Inc.
Address:	17-25 Hunter Place Fair Lawn, New Jersey 07410
Phone:	(201) 794-7999
Fax:	(201) 794-7958
CONTACT PERSON:	Richard E. Lippman, O.D., F.A.A.O. Official Representative and Correspondent R.P. Chiacchierini & Associates, LLC 15825 Shady Grove Road Suite 30 Rockville, Maryland 20850
Phone:	(240) 683-3738
FAX:	(240) 683-9236

DATE SUMMARY PREPARED: November 10, 2003

TRADE NAME: **NoveLens®** Contact Lens Case

COMMON NAME: contact lens case
CLASSIFICATION: Class II: LRX

ESTABLISHMENT REGISTRATION: PENDING

SUBSTANTIALLY EQUIVALENT TO:

The NoveLens® Contact Lens Case is substantially equivalent to the following devices:

K013232	Bausch & Lomb CyberCase Contact Lens Case
K852384	Basuch & Lomb CyberCase Contact Lens Case
K971618	Alcon Contact Lens Case
K974281	Alcon Contact Lens Case
K021248	iCase: IKeeps, Inc.

DESCRIPTION of the DEVICE:

The NoveLens® Contact Lens Case is a contact lens storage case comprised of a plastic case that houses two chambers. The upper chamber which holds the lenses separately in individually attached concave reservoirs and a lower chamber that provides space for rinsed solution as it passes through holes from the upper chamber and through a drainage tube into

the lower portion of the device. The NoveLens® Contact Lens Case is constructed to take solution introduced into the upper chamber in a rinse fashion and force, by gravity, solution through the drainage holes through a drainage tube and into a lower collecting chamber. Additional solution is added until both chambers are completely filled to the top. Screw caps when closed hermetically seal the system to hold disinfection solution while the lenses are stored and disinfected in accordance with directions consistent with labeled multipurpose contact lens solutions. The design provides for one-way ingress of solution and expulsion of spent solution through external drainage holes from the lower chamber upon tipping the unit on its side.

INDICATIONS FOR USE:

The NoveLens® Contact Lens Case is indicated for storage of hard, rigid gas permeable (silicone acrylate and fluro silicone acrylate) and soft (hydrophilic) contact lenses during chemical disinfection.

ACTIONS:

The NoveLens® Contact Lens Case provides for lens storage during chemical disinfection as well as storage up to the labeled time listed on the user's multipurpose disinfection solution. Directions for use accompany the NoveLens® Contact Lens Case for continued safe use of the device.

TOXICITY TESTING

A battery of toxicology tests were conducted on the plastic components to verify the safety of the materials used in the device. The tests included Cytotoxicity, Ocular Irritation, and Systemic Toxicity in conformance with FDA Guidance for contact lens case products: Guidance for Industry-Premarket Notification 510(k) Guidance Document for Contact Lens Care Products- dated May 1, 1997, and ISO-10993-1.

Results of the testing demonstrate that the safety and effectiveness of the NoveLens® Contact Lens Case is equivalent to the predicate devices listed above.

EFFECTIVENESS TESTING for the NoveLens® Contact Lens Case

No further testing for case effectiveness was warranted for demonstration of substantial equivalence.

CLINICAL INFORMATION

Clinical studies were deemed unnecessary as the solutions used in the NoveLens® Contact Lens Case are already cleared for marketing as cleaning, rinsing, disinfection, and storage solution for soft, RGP, and hard contact lenses.

LABELING

The NoveLens® Contact Lens Case is provided to the user with an outer carton as well as User Instructions.

NoveLens® Inc.
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Fair Lawn, New Jersey 07410
(201) 794-7999
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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC - 4 2003

NoveLens®, Inc.
C/O Richard Lippman, O.D., F.A.A.O.
Vice President, Ophthalmic Regulatory Medical Products
R.P. Chiacchierini & Associates, LLC
15825 Shady Grove Rd., Suite 30
Rockville, MD 20850

Re: K032309
Trade/Device Name: NoveLens® Contact Lens Case
Regulation Number: 21 CFR 886.5928, 21 CFR 886.5918
Regulation Name: Soft (hydrophilic) contact lens care products, Rigid gas permeable contact lens care products
Regulatory Class: Class II
Product Code: LRX
Dated: November 10, 2003
Received: November 10, 2003

Dear Dr. Lippman:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4613. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

A. Ralph Rosenthal

A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indication Statement

510(k) Number (if known): K032309

Device Name: NoveLens® Contact Lens Case

Indications for Use:

The NoveLens® Contact Lens Case is indicated for storage of hard, rigid gas permeable (silicone acrylate and fluro silicone acrylate) and soft (hydrophilic) contact lenses during chemical disinfection.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)
Concurrence of CDRH, Office of Device Evaluation (ODE)

Presription Use _____ OR Over -The-Counter Use X JS

(Oprtional Format 1-2-96)

Karen Warbington

(Division Sign-Off)
Division of Ophthalmic Ear,
Nose and Throat Devises

510(k) Number K032309